REMARKS/ARGUMENTS

Claims 11-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pearlman et al. (WO/9918800) in view of Huet et al. (U.S. 6,426,333). This rejection is respectfully traversed.

Applicant has submitted an argument in response to this rejection in the Response dated May 26, 2009. Applicant submits a further argument below.

As recited in the independent Claim 11, Applicant's claimed dermatological composition consists of an avermectin compound in a concentration from about 0.05% to about 0.1% (w/v) in a lotion comprising glycerin, hydrogenated polyisobutene, cetearyl alcohol, polyoxyethylene ether of cetyl and stearyl alcohol, macadamia nut oil, dimethicone, tocopheryl acetate, stearoxytrimethylsilane, stearyl alcohol, panthenol, farnesol, benzyl alcohol, phenoxyethanol, acrylates/C10-30 alkyl acrylate crosspolymer, sodium hydroxide, citric acid, and water.

As discussed previously, Applicant's claimed composition is used for treating various forms of dermatological conditions, which requires daily application for a substantial period of time, i.e., from several weeks to several months. Applicant has discovered that the instant dermatological composition containing a very low concentration of ivermectin from 0.05% to 0.1% is effective in treating various dermatological conditions without causing skin irritation, or increase of skin sensitivity after daily use of the instant composition for a substantial period of time up to several months (see Examples 4-14, particularly Example 9).

Furthermore, in addition to the active ingredient of ivermectin, the lotion used in the dermatological composition is a moisturizing lotion that itself does not cause skin irritation.

Therefore, Applicant's topical composition containing a very low concentration of ivermectin in such a lotion as defined in Claim 11 has strong clinical advantages in treating the dermatological conditions described above.

In the response dated May 26, 2009, Applicant has pointed out that Pearlman et al. teach away from Applicant's claimed composition because Pearlman et al. teach the ivermectin concentration from about 0.25% to about 2.5% to be effective (see page 6, third paragraph).

In this response, Applicant further points out that in terms of the lotion used in the topical composition Pearlman et al. further teach away from Applicant's claimed composition. More specifically, Pearlman et al. teach to use Cetaphil® Cleanser as a pediculostatic agent and ivermectin as a pediculocide. It is important to understand that Cetaphil® Cleanser is a distinctly different product and has a distinctly different composition from Cetaphil® moisturizing lotion. For the convenience of discussion, Pearlman et al.'s teaching is recited below (p18, line 9 to page 19, line 2).

> The most preferred composition for use as a pediculostatic agent in the invention is a mixture of water, cetyl alcohol, propylene glycol, sodium lauryl sulfate, stearyl alcohol, methyl paraben, propylparaben, and butylparaben sold commercially as a nonirritating, non-greasy skin Cleanser under the trademark CETAPHIL® Cleanser (Galderma Laboratories, Inc., Fort Worth, TX).
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> CETAPHIL® Cleanser is additionally advantageous since it aids in the removal of the nits. While the mechanism for this property is not fully understood, a component or components in CETAPHIL® Cleanser may dissolve or loosen the cement which holds the nits to the hair shaft, and may also make the shaft slippery, thus facilitating the removal of the nits during combing.
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> CETAPHIL® Cleanser has the ability to rapidly trigger the "immersion reflex" in head lice. Both *in vivo* and *in vitro*, lice coated in CETAPHIL® Cleanser became immobilized within 6 seconds. On the patients' scalp, the lice became totally immobilized, floating on the scalp in the Cleanser. They were easily removed by forceps without any effort to escape or to grasp the hair shaft to stay in place. Under the microscope, they were immobile, did not respond to being touched, and lost their normally visible gut motility. They remained immobilized as long as they were in the Cleanser. This phenomenon was observed for periods ranging from 6 seconds to 4 hours. At any point the louse could be removed from the Cleanser and usually awakened and resumed crawling. When immersed overnight in CETAPHIL® Cleanser (12 hours) the lice died.

Furthermore, in all examples (Examples 1 through 7) Pearlman et al. demonstrate their invention using Cetaphil® Cleanser manufactured by Galderma Laboratories, Inc.

As taught by Pearlman et al., Cetaphil® Cleanser contains water, cetyl alcohol, propylene glycol, sodium lauryl sulfate, stearyl alcohol, methylparaben, propylparaben, butylparaben (page 18, lines 9-15, see above). This composition is substantially different from the lotion defined in Claim 11 of the present application.

As disclosed in the examples of the instant Specification, the lotion used in the dermatological composition in one embodiment of the present invention is the Cetaphil® moisturizing lotion manufactured by Galderma Laboratories, Inc. (see page 24, lines 1-14 of the Specification).

It must be understood that Cetaphil® moisturizing lotion is distinctly different in chemical composition, property and function from the Cetaphil® Cleanser from the same manufacturer. Applicant submits herewith the product descriptions from Galderma in Exhibits, which are available publically. Exhibit A is the product description of Cetaphil® moisturizing lotion, and Exhibit B is the product description of Cetaphil® Gentle Skin Cleanser which has the same composition disclosed by Pearlman et al.

As specifically shown by the manufacturer, Cetaphil® moisturizing lotion is non-comedogenic, and does not contain fragrance, lanolins or parabens that could irritate sensitive skin. However, for the purpose of cleansing Cetaphil® Cleanser contains chemicals that are not suitable for the moisturizing lotion, for example, sodium lauryl sulfate and three different parabens. As can be appreciated, this composition is intended to wash face, and is not suitable as a medium of a dermatological composition, which will stay on the skin after application and will be applied for a substantial period of time for treatment of dermatological conditions.

Therefore, in terms of the medium of the dermatological composition, Pearlman et al. teach away from Applicant's claimed composition that can be used for treating various conditions without causing skin irritation, or increase of skin sensitivity after daily use for a period of time.

With regard to Huet et al., an argument has been provided previously.

Moreover, Applicant further submits that since Pearlman et al. fail to teach the chemical composition of the lotion as defined in Claim 11, one of ordinary skill in the art would have no reason to combine Pearlman et al. with Huet et al, in the manner suggested by the Examiner, in order to obtain Applicant's claimed invention. Even if one combines, one would not obtain the dermatological composition as defined in Claim 11.

Therefore, Applicant maintains that Applicant's claimed dermatological composition defined in Claim 11 is unobvious in view of the prior art of record.

With regard to Claims 12-16, these claims are dependent upon independent Claim 11. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claim 11 is not obvious, as such Claims 12-16 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §103(a).

It is respectfully submitted that Claims 11-16, the pending claims, are now in condition for allowance and such action is respectfully requested.

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

June 24, 2009
Date of Signature

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